PUBLIC HEALTH COUNCIL

Meeting of the Public Health Council, Tuesday, December 16, 2003, 10:00a.m., Massachusetts Department of Public Health, 250 Washington Street, Boston, Massachusetts. Public Health Council Members present were: Chair Christine Ferguson, Commissioner, Department of Public Health, arriving late [approximately 10:20 a.m.]; Ms. Suzanne B Thomson, Deputy Commissioner, Acting Chair; Dept. of Public Health; Ms. Maureen Pompeo; Mr. Albert Sherman; Ms. Janet Slemenda; Dr. Thomas C. Sterne, Mr. Gaylord B. Thayer, Jr.; and Dr. Martin J. Williams. Ms. Phyllis Cudmore and Mr. Manthala George, Jr. were absent. Attorney Donna Levin was present as General Counsel.

Acting Chair, Suzanne Thomson, announced that notices of the meeting had been filed with the Secretary of the Commonwealth and the Executive Office of Administration and Finance, in accordance with the Massachusetts General Laws, Chapter 30A, Section 11A ½. In addition, the Deputy Commissioner announced New Business: Additional appointments and reappointments to the medical staff of Lemuel Shattuck Hospital, letter of December 8, 2003; and the addition of a Staff Presentation entitled, "A Comprehensive Report on Influenza and the Status of Influenza Vaccine in Massachusetts", by Dr. Alfred DeMaria, Assistant Commissioner, Bureau of Communicable Disease Control, Dr. Susan Lett, Medical Director, Immunization Program and Dr. Bruce Auerbach, Vice President and Chief of Emergency and Ambulatory Services, Sturdy Memorial Hospital.

The following members of the staff appeared before the Council to discuss and advise on matters pertaining to their particular interests: Dr. Alfred DeMaria, Assistant Commissioner, Bureau of Communicable Disease Control; Dr. Susan Lett, Medical Director, Immunization Program; Ms. Louise Goyette, Director, Office of Emergency Medical Services; Dr. Grant Carrow, Director, Drug Control Program; Ms. Brunilda Torres, Director, Multi-Cultural Health; Dr. Paul Dreyer, Interim Assistant Commissioner, Center for Health Quality Assurance and Control; Ms. Joyce James, Director, Mr. Jere Page, Senior Analyst, Determination of Need Program; and Attorney Howard Saxner, Deputy General Counsel, Office of the General Counsel.

PERSONNEL ACTIONS:

REQUEST APPROVAL OF APPOINTMENTS AND REAPPOINTMENTS TO THE VARIOUS MEDICAL STAFFS OF TEWKSBURY HOSPITAL:

In a letter dated December 8, 2003, Katherine Domoto, M.D., Associate Executive Director for Medicine, Tewksbury Hospital, Tewksbury, recommended approval of appointments and reappointments to the various medical staffs of Tewksbury Hospital. Supporting documentation of the appointees' qualifications accompanied the recommendation. After consideration of the appointees' qualifications, upon motion made and duly seconded, it was voted (unanimously): That, in accordance with the recommendation of the Associate Executive Director for Medicine of Tewksbury Hospital, under the authority of the Massachusetts General Laws, Chapter 17, Section 6, the following appointments and

reappointments to the various medical staffs of Tewksbury Hospital be approved for a period of two years beginning December 1, 2003 to December 1, 2005:

APPOINTMENTS:	**STATUS/SPECIALTY:**	**MED. LICENSE NO.:**
John Martin-Joy, MD	Active Psychiatry	210262
Michele Masi, MD	Consultant Neurology	53825

REAPPOINTMENTS:	**STATUS/SPECIALTY:**	**MED. LICENSE NO.:**
John Davidson, MD	Consultant Pulmonology	33520
Dov Fogel, MD	Affiliate Psychiatry	156539
Sanjay Kamath, MD	Consultant Radiology	81929
Wayne Pasanen, MD	Consultant Emergency Medicine	35507
Venkata Satyam, MD	Affiliate Internal Medicine	53327

REQUEST APPROVAL OF INITIAL APPOINTMENTS AND REAPPOINTMENTS TO THE MEDICAL AND ALLIED HEALTH PROFESSIONAL STAFFS OF LEMUEL SHATTUCK HOSPITAL:

In letters dated November 17, 2003, and December 8, 2003 (New Business), Paul D. Romary, Executive Director, Lemuel Shattuck Hospital, Jamaica Plain, recommended approval of initial appointments and reappointments to the medical and allied health professional staffs of Lemuel Shattuck Hospital. Supporting documentation of the appointees' qualifications accompanied the recommendation. After consideration of the appointees' qualifications, upon motion made and duly seconded, it was voted (unanimously): That, in accordance with the recommendation of the Executive Director of Lemuel Shattuck Hospital, under the authority of the Massachusetts General Laws, Chapter 17, Section 6, the appointments and reappointments to the medical and allied health staffs of Lemuel Shattuck Hospital be approved as follows:

APPOINTMENTS:	**STATUS/SPECIALTY:**	**MED. LICENSE NO.:**
Mark Amorsino, MD	Consultant Internal Medicine	216259
Elena Sharipova, MD	Consultant Psychiatry	213158
Joseph Polak, MD	Consultant Radiology	46031
Shoba Sequeira, MD	Consultant Radiology	40122
Constance Ebong, MD	Consultant Psychiatry	217055
Maitri Patel, MD	Consultant Psychiatry	217414
David Dodson, MD	Consultant Internal Medicine	46147
Michael Stephen, MD	Consultant Internal Medicine	218560
Eric Uyguanco, MD	Consultant Internal Medicine	217361
Henry Mitcheson, MD	Consultant Urologic Surgery	48820
Hussam Batal, DMD	Consultant Dentistry	20681

REAPPOINTMENTS:	**STATUS/SPECIALTY:**	**MED. LICENSE NO.:**
Mark Bankoff, MD	Consultant Radiology	37557
Ina Bhan, MD	Consultant Pathology	38417
Homa Safaii, MD	Consultant Pathology	34341
Barbara Weinstein, MD	Consultant Pathology	45724
Carl Fulweiler, MD	Active Psychiatry	80208
Jean Ramsey, MD	Consultant Ophthalmology	79890
Gina Terenzi, DMD	Consultant Dentistry	18400
Muthoka Mutinga, MD	Active Internal Medicine, GI	153759
Raphael Altieri, MD	Consultant Radiology	157787
Robert Sarno, MD	Consultant Radiology	33484
Robert Salomon, MD	Consultant Pathology	52936
Richard Miller, MD	Consultant Dentistry	14060

Allied Health Professional – Appointment
Dennis Tyrell, PhD – Department of Psychiatry #8124

Allied Health Professional – Reappointments
Ruth Haskal, NP – Medicine #108448
Mary Keohane, NP – Medicine #155670
Virginia McCullough, PA – Medicine #512

Note: Chair Ferguson arrived after the personnel items were heard. She presided over the rest of the meeting. In addition, at this time, Rep. Charles Murphy testified in support of the Lahey Clinic application – see Lahey Clinic application for his comments.

NEW BUSINESS:

PRESENTATION:

"A COMPREHENSIVE REPORT ON INFLUENZA AND THE STATUS OF INFLUENZA VACCINE IN MASSACHUSETTS", BY DR. ALFRED DEMARIA, ASSISTANT COMMISSIONER, BUREAU OF COMMUNICABLE DISEASE CONTROL, DR. SUSAN LETT, MEDICAL DIRECTOR, IMMUNIZATION PROGRAM AND DR. BRUCE AUERBACH, VICE PRESIDENT AND CHIEF OF EMERGENCY AND AMBULATORY SERVICES, STURDY MEMORIAL HOSPITAL:"

Dr. Alfred DeMaria, Assistant Commissioner, Bureau of Communicable Disease Control, said in part, "…I think what we are experiencing is a somewhat worse influenza year. We don't know the full impact of this yet, but in other parts of the country, the impact has been substantial and we have to assume that the impact here will be much more marked than we have experienced in the past few mild flu seasons. We are at a point now, relatively early on into the flu season, of

having regional flu activity, and the CDC defines flu activity on the basis of a scale going from sporadic to local, to regional, to widespread, and up until recently, that was a subjective determination. Now it is dependent on cases, clusters, and isolation of sporadic to local, to regional. The progression is very recent for Massachusetts. This flu season was one of the earliest flu seasons to start with, beginning several months ago in the west and southeast part of the country. They have had a very large number of influenza cases already and we are just at the point now of regional activity. Where this will go is not always predictable -- when we will see the peak in flu activity, but we are certainly heading for the peak, perhaps earlier than we have in other years, where the peak is usually January and February."

Dr. DeMaria continued, "Besides the unusual early start to the influenza season nationally this year, we are also dealing with genetic drift in the virus. Every year the flu virus changes, and every year in February and March there is a determination as to what the most likely strains of flu to be circulating in the coming season will be, and the vaccine is designed for that purpose….There has been some change in the virus that makes the vaccine less active against the virus than would be expected, not that it is not protective. I think it is very important that there is protection from the vaccine, it is just not at the level of protection that would have been expected if the Panama strain had continued to be the strain of this virus circulating. What we are seeing this year is an early start and a drift in the virus, similar to what we experienced back in 1997…The unusual aspects of this year are the early start and the drift in the virus."

Chair Ferguson said, "I want to reiterate one point that Dr. DeMaria has made, and that coincides with some of the questions that I have been asked. If there is a strain of the flu that the vaccine does not cover, what is the point in having the vaccine? And so, I want to be very clear that the vaccine is protective. There is a strain that it is not particularly protective of. However, if people in large scale did not have the vaccine, we would have a much worse situation than we have now. So, people should not take this to mean that the vaccine is not effective at all during the flu season. I think that is very important…"

Dr. DeMaria added, "…And the other point is, there are three viruses in the vaccine. Three viruses are represented. So, it does provide protection against the other viruses that are circulating…So, the vaccine is still active against this virus, and is still the best protection we have. Unfortunately, the supply is limited. It is all out there. It is not in the manufacturer's and the distributor's hands anymore. It's out in the community. Because of the early start of the flu season, and because of the demand for the vaccine, that supply has been limited, even though it was the same amount manufactured last year. The other aspect of this season is, there is an approved vaccine, the FluMist vaccine. People between the ages of five to forty-nine who have no underlying medical conditions can receive the nasal flu vaccine. It is a live virus vaccine. That is why it is somewhat limited in its utilization, but it is as effective as the injectable vaccine. It is a good option for people who are not in high risk groups because right now we are focusing the available supplies of injectable vaccine on the people who are most at risk of severe complications of influenza, and that is people over 65, people at any age who have significant underlying medical conditions; heart disease, lung disease, and children between the ages of six to twenty-three months, as well as pregnant women in the second and third trimester. All of these individuals have a higher risk of severe complications of influenza, and that is why we have to focus on their immunization first. We always have focused on the immunization of high

risk individuals first, and we continue to do that. People between the ages of five to forty-nine can avail themselves of the FluMist vaccine, the nasal vaccine."

Chair Ferguson added, "To clarify on the FluMist, most of our health plans in the state are covering FluMist, which I think is a testament to their understanding of the importance of this. We are working with Medicaid. Medicaid right now has FluMist on a 24-hour prior approval status, but we are working with them to take that off, so that FluMist will be available to the Medicaid population, as well. Everyone should do everything they can to protect themselves against the virus."

Dr. Susan Lett, Medical Director, Immunization Program followed. She made a slide presentation, showing the latest data from the CDC on influenza activity in the United States. She said, "This is the earliest activity we have seen since 1976. Right now, 24 states, mostly in the western part of the country, are reporting widespread activity; 15 regional, six local and five sporadic. Influenza-like illness, which is just really sort of the symptoms of influenza that get reported by a network of sentinel physicians and we have thirty-three that participate in Massachusetts, is a way we look at activity around the country, as well, and right now about five percent of the illness that providers are seeing in their office is influenza-like, and the baseline for this time of year would be about 2.5%. In terms of deaths, which is another parameter that we use to monitor flu activity, overall, deaths are only at 7 percent, and that is below the historic baseline of about 7.9% at this time in the year. Although we have been hearing reports about pediatric deaths, which we of course are monitoring quite carefully, overall deaths are not above baseline. That being said, there have been reports, in the press and also in literature about pediatric deaths, and right now there have been 38 so far, from 12 states, mostly in the western and south central part of the country. About half the children had risk factors and half were healthy. Very few were vaccinated. There have been reports of 88 pregnant women hospitalized in the Dallas area. Pregnant women are known to be at risk for influenza, but this year that does appear to be a little bit more severe than usual. What is hard for us to sort out is that we don't really monitor pediatric deaths and we don't monitor encephalitis and illness in pregnant women to the extent that it has been reported this year. It is hard for us to sort out, is this something new happening, or is it just better reporting…In order to be ready for the next flu pandemic, CDC has asked states to enhance reporting. Massachusetts and other states have done that."

Dr. Lett noted that 99% of the flu strains are AH-3 and 2, and of that 72% is the Fujian strain. Discussion continued, and it was noted that we are the last part of the country to experience flu season, peaking here in mid-February. Chair Ferguson summed up the situation, "The season is earlier. There is a strain that is not covered by the vaccine, that causes us to be concerned, and the fact that we have not had that serious an outbreak for some time means that we are due for it. Even though we are not in a crisis, all of these things lead us to being very concerned and wanting people to understand how important it is to practice good preventive hygiene and behavior, and to get the flu vaccine or FluMist so that we can damper the impact." Dr. Lett concurred. Dr. Lett further noted, that providers have been notified about who their priority patients should be, those at high risk: young children, people over 65 years of age, pregnant women and people with underlying conditions. The second tier for prioritization of vaccine would be the people who take care of those high risk people, because they can transmit the disease -- that includes household members, as well as health care workers. "There are three

million doses of FluMist available in the United States which is an excellent option for healthy people", staff said.

Discussion continued Dr. Lett noted in response to one of Dr. Sterne's questions that it takes from one to two weeks after being vaccinated to be protected from the flu. Dr. Lett noted the hallmarks or things parents can look for with the onset of the flu: the sudden onset of the symptoms, fever as high as 104, sore throat, dry cough, myalgia and fatigue.

Staff noted that if one should get the flu, protect yourself in the following ways:

- Rest
- Drink plenty of fluids (at least one glass for every hour) to prevent dehydration and to prevent fevers from rising
- Take medication for both pain control and fever control such as Tylenol, Advil or Motrin; no aspirin for the children (i.e., children and teenagers could develop Reye's Syndrome from aspirin)
- Stay home for at least five days (that is how long the average person is infectious but one should really stay home until symptoms are resolved)
- Avoid alcohol and tobacco

Staff noted other Prevention Strategies to avoid the flu:

- Wash your hands often during the day (use alcohol rubs or gels if you are not near a sink)
- Avoid touching your nose and mouth (so you won't acquire influenza through your respiratory tract)
- Turn your head and use a tissue when you cough or sneeze and dispose of tissues carefully
- Avoid close contact with high risk individuals
- Don't take children or people with weakened immune systems into large crowds or gatherings
- Don't share items such as straws, drinking cups, glasses or bottles
- Clean commonly touched surfaces in your home, classroom or child care setting such as door handles, telephones, and water faucets

<u>One should seek medical help if</u>:

- If you have severe or prolonged illness
- If you have rapid or labored breathing
- If your skin turns bluish
- If you have flu symptoms, you improve, and then become ill again with a fever and a cough that is productive, that is something comes up with an unpleasant color, any color other than clear

<u>In addition, for a child look for:</u>

- Irritability that is not normal
- The child doesn't want to be held or touched
- Decreased fluid intake
- Or the child is not waking-up or interacting

In closing, Dr. Lett said in part, "….What are we doing this year? We are working with all of our partners for a vaccine prioritization and redistribution. We have redistribution now of over two thousand doses that we have identified to go to the highest risk patients in people's practices. We are collaborating with professional organizations and our other partners to get the word out about prioritization and flu vaccine. We are working on hospital emergency department capacity planning and informing the public with the same information we presented today. We have a 24-hour hotline and information on our web site."

Dr. Bruce Auerbach, Vice-President and Chief of Emergency and Ambulatory Services, Sturdy Memorial Hospital, addressed the Council. Dr. Auerbach said in part, "…There is no question that it is out there [flu], but the importance of stressing the issues around appropriate hygiene, appropriate cough etiquette, I know that the Department has recommended, and many of the institutions have actually started laminating informational cards about cough etiquette, and putting them at every entry point to the institution. The other thing that I think is a very important bit of information that we provide is that, as a society, I think we have always felt that it was sort of macho to go to work sick. Most of us, as we are raising children, would make it very clear that our kids couldn't go back to school until at least twenty-four hours after the fever was gone, and yet most of us will probably go to work with fever because we don't feel sick enough to not do it, and we don't really take into account the public health and the communicable disease issues that are related. You may not feel sick, but you may certainly be bringing something into the work place, or into a crowded environment, that can affect other people, many of whom may have less immunologic ability to fight an infection than you do. We have been stressing that, when you are sick, you need to stay home, and you need to remove yourself from public places if at all possible, and limit the amount of contact you have with

kissing and sharing implements, and things of that nature. We have been working very hard to support the Department's initiatives and activities at the local level."

Dr. Auerbach continued, "I think it is fair to say that the emergency departments and the physician practices around the state are getting slammed. Our volume, at my own institution, we are probably up about seven percent over the same month last year, over the same time last year, and the majority of those individuals are coming in with flu-like illness….Just one more bit of information that I want to make sure the Council knows and the public. Most of the hospitals now have started very aggressively a triage in the Emergency Department, masking any patients that come in with respiratory illnesses, or respiratory complaints, and I think it is important that people know that is probably going to happen to them, that they may be sitting next to people in waiting rooms with masks on, and that should not really raise them to a level of hysteria. It is a normal communicable disease precaution because these things have spread by droplets, and the best way to reduce that is to reduce it at the source by putting a mask on individuals."

Discussion continued and it was noted that if a physician has a patient of high risk for flu. He/she should consult with their local community health center for vaccine, where most of the Department's vaccine went. The Department's number for the vaccine unit that a physician can call to try to locate vaccine is (617)983-6828. The general public should call (866) 627-7968.

NO VOTE/INFORMATION ONLY

PROPOSED REGULATIONS:

INFORMATIONAL BRIEFING ON AMENDMENTS TO 105 CMR 170.000: EMERGENCY MEDICAL SERVICES SYSTEM, REGARDING ACCREDITATION OF EMS TRAINING INSTITUTIONS:

Ms. Louise Goyette, Director, Office of Emergency Medical Services, presented the amendments to 105 CMR 170.000. She said, "EMS 2000 did not greatly change things for the training and certification of EMS personnel, but one important thing that it does do is to lay down the groundwork to sort of get the approval and the quality pieces of Training and Education under the umbrella of accredited training institutions. The number of objectives here are really to build on the infrastructures of many of our academic institutions in the Commonwealth that already do training and education for EMS personnel, to make sure that we have a quality management structure within training and certification, to clarify roles and responsibilities, that normal kind of thing that comes with statutory changes. One of the most important things to me is with accreditation, the opportunity to merge the interests of training providers with the interests of the actual care providers, which is something that really is not happening now. It needs to happen, both from a program content or a curriculum content perspective, what needs to be taught and what do EMTs need to know about as we work in an ever-evolving health care climate, and also to address the timeliness of process issues. There are some substantial benefits to getting Training and Education under larger umbrellas and get them under the umbrellas of already academically, or already recognized academic and educational institutions. For us, it means transitioning some six thousand individual courses that are assessed for quality only via a

paper audit. It is an extremely administrative process. One has to question the ultimate benefit of that process."

Ms. Goyette continued, "The other thing is to reduce the amount of time from the time someone completes an initial training program to the time that they are through the certification process, by moving the practical skills portion of the certification exam into the accredited training institution environment. That completes a cycle. We have already outsourced the written exam, and cut about four to six weeks off there. We estimate we will be reducing the time interval by another four to six weeks by actually moving the practical skills exam more proximal to the course end. Another benefit or administrative benefit is a substantial cost reduction for the Department, close to two hundred thousand dollars in costs that we currently incur by actually hiring examiners that academic institutions will now hire, and defray through their own test administration fee process. And also, I think for me personally within the office, is to be able to take what is an extremely veteran staff and to better utilize them, and to ensure quality in training programs. The accreditation program has been developed in conjunction with our Emergency Medical Care Advisory Board. We recently had a comment period for the Emergency Medical Care Advisory Board. A lot of folks did not testify but in general, comments to us informally have been very positive. We sort of spawned this idea in conjunction with training institutions themselves. I just want to call your attention to some of the other kinds of technical changes that are in this particular set of regulations. There are probably four that are worthy of note, other than typos and that kind of thing. We do a tremendous amount of regulatory development. One of the changes we are making in the Serious Incident Reporting Requirements, we had a requirement that, if there was a third occurrence in a year, it triggered a certain process. Since nobody can really define what a year is or what kinds of occurrences need to be included in that group, we are actually deleting that language. We haven't enough history with the serious reporting to justify it. One of the substantial things we are doing, and it is an unfortunate reflection of reality, is we are actually adding assessment to a key piece of regulation, section 355, which is the section that defines an ambulance service's responsibility to dispatch, treat, and transport. We have enough compliance cases to suggest that we need a clear foundation of regulations that EMS personnel's first job is to assess a patient, and we are adding remedial training explicitly to the regulations as a part of the enforcement action conundrum.

NO VOTE/INFORMATION ONLY

INFORMATIONAL BRIEFING ON AMENDMENTS TO 105 CMR 700.000: IMPLEMENTATION OF M.G.L.c.94C:

Dr. Grant Carrow, Director, Drug Control Program, accompanied by Deputy General Counsel, Howard Saxner, presented proposed amendments to 105 CMR 700.000 to the Council. Dr. Carrow noted in part, "The Drug Control Program is proposing regulations to address administration of epinephrine and nerve agent antidotes by certain certified individuals as well as trained first responders and other non-medical staff utilizing autoinjectors in emergencies involving anaphylaxis or nerve agent release. The proposed regulations would permit:

1. Authorized public employees, whose functions include emergency preparedness and response, including first responders, to administer prescribed epinephrine and approved

nerve agent antidotes for force protection.

2. Authorized staff in state funded, operated or licensed programs to administer prescribed epinephrine to individuals served by such programs.

3. Certified EMS First Responders (EFRs) to administer epinephrine to the public.

4. Authorized first responders to administer epinephrine to the public.

Dr. Carrow noted the rationale for the changes to the regulations: He said in part, "Increasing concern about anaphylaxis, particularly among children and young adults, has placed emphasis on the need for improved emergency response mechanisms for programs operated by or overseen by the Commonwealth. Similarly, increasing focus on preparedness for municipal and public agency response to potential bioterrorism incidents has pointed up the need to have mechanisms in place to deliver nerve agent antidotes quickly to emergency workers for force protection. The Department of Youth Services (DYS) brought to our attention both the increasing number of clients in its custody with a history of anaphylaxis and the increasing incidence of anaphylaxis events. None of its 60 residential programs has more than 40 hours a week of on-site nursing coverage and nearly a third have no on-site medical or nursing staff. Moreover, there are no DYS settings within less than 5 minutes of EMS arrival time anywhere in the state and several residences are located in rural sites more than 15 minutes out from EMS. Emergencies involving anaphylaxis or exposure to nerve agents often require response times that are less than can be provided by EMS services. Potential morbidity and mortality from such incidents could be reduced if those first on the scene were able to administer epinephrine to individuals experiencing anaphylaxis or antidotes to partners and colleagues exposed to nerve agents, for force protection. The regulations proposed here expand the capacity of staff in public agencies, including first responders, to respond to such emergencies in the time prior to EMS response."

Dr. Carrow continued, "Epinephrine, the major treatment for anaphylaxis, and pralidoxime chloride and atropine, the combination antidote to organophosphate nerve agents, are available in dose-metered auto-injectors designed for self-administration. Because these devices do not require measuring or syringes to manipulate, they are simple, easy-to-use, and enable a rapid and accurate dosing of medication, even if the affected person is in protective clothing. Currently, there is no regulatory impediment to self-administration using these devices. Authorized, appropriately trained individuals should likewise be able to safely administer these pharmaceuticals to their partners, colleagues and charges using auto-injector devices. Similarly, appropriately trained first responders should be able to administer epinephrine to individuals experiencing anaphylaxis. The benefits of administering these life-saving pharmaceuticals outweigh any risks of possible inappropriate or unnecessary administration."

In conclusion, Dr. Carrow noted, "that to facilitate emergency preparedness by municipalities and public agencies of the Commonwealth, we propose a new registrant category encompassing municipalities and non-municipal public agencies. All municipalities and non-municipal public agencies that wish to authorize certain of their employees or employees of programs that they fund, operate or license to administer epinephrine or antidotes must be registered with the Department. A licensed practitioner would be named on the Massachusetts Controlled

Substances Registration to assume responsibility for compliance with Department guidelines. The proposed regulations would require that all auto-injectors containing epinephrine or antidotes be administered pursuant to the order of a practitioner. In the case of prescribed epinephrine, this requirement would be satisfied by the prescription and any additional instructions from the prescriber. In the case of non-prescribed epinephrine and other antidotes, we expect that standing orders would be used, including the Statewide Treatment Protocols for EMS and EFR personnel and first responders. The regulations would require establishment of protocols and procedures, conduct of trainings, retrainings and evaluations and maintenance of records, among other requirements. These requirements would ensure that personnel are able to readily recognize the signs and symptoms of an anaphylactic reaction or nerve agent poisoning and to treat others in a safe, timely and effective manner. Additional changes to the regulations are necessary to maintain consistency with the changes that the Department has made to its Emergency Medical Services System regulations. This includes authorizing administration of Schedule VI controlled substances by a new category of certified Emergency First Responders (EFRs) and of epinephrine by first responders (police, fire). The Drug Control Program intends to proceed to public hearing on the proposed changes to 105 CMR 700.000."

NO VOTE/INFORMATION ONLY

REGULATIONS:

REQUEST FOR FINAL PROMULGATION OF 105 CMR 721.000: STANDARDS FOR PRESCRIPTION FORMAT AND SECURITY:

Dr. Grant Carrow, Director, Drug Control Program, presented the final recommended amendments to 105 CMR 721.000. Dr. Carrow said, "The purposes of this set of regulations is to permit electronic prescribing in the Commonwealth and to ensure that the appropriate protections for the public health and safety are in place, so that we can realize the full potential of electronic prescribing, to actually prevent or at least reduce prescription fraud, medication errors, and other problems that we engender with prescriptions today. This will be an added option. It will not be mandatory. It is voluntary to everyone who wants to use it, who is involved in the communication of prescription information, and all the mechanisms that we have today for prescribing will still remain in place. We do hope, however, that people gravitate toward this kind of process because it does have that great potential that I mentioned. We have met with you in October. We have had a public hearing. We have met with industry representatives, and worked out some of the technical details that they recommended. We agree with those and as far as we understand, the industry is happy about the agreement and the balance that we have been able to meet between the capability of enabling electronic prescribing in Massachusetts and our continuing insistence that we protect the public health."

After consideration, upon motion made and duly seconded, it was voted: (unanimously): [Dr. Sterne and Mr. Thayer were not present to vote] to approve the request for Final Promulgation of 105 CMR 721.000: Standards for Prescription Format and Security; that the approved regulations be forwarded to the Secretary of the Commonwealth; and that a copy be attached and made a part of this record as **Exhibit No. 14,772**.

PROJECT APPLICATION NO. 4-3A58 OF LAHEY CLINIC HOSPITAL:

Representative Charles Murphy of the Massachusetts General Court, representing Burlington, Wilmington and Bedford, Massachusetts, addressed the Council. He said in part, "…One of the biggest issues and reasons why I am hopeful that it will get its approval here and on the local level is the issue of diversion with ambulances. This expansion will allow for Lahey to accept more ambulance runs and be able to take in more folks who need the support. In addition, the proposed expansion also includes a larger cancer center, and some other items, which again are needed in the big picture. Lahey Clinic is a world leader and this will only allow it to continue to be a world leader. You are going to hear from the CEO, David Barrett, who will give you the details of the expansion, and I just would ask and I am hopeful that you would look favorably upon their request…"

Jere Page, Senior Analyst, Determination of Need Program, presented the Lahey Clinic application to the Council. He said, "…Lahey is seeking approval for new construction and renovation on the hospital's campus in Burlington. The new construction involves a two-story addition on top of the existing southeast wing to increase the hospital's medical/surgical bed capacity from 227 to 263 beds. That is an increase of 36 beds, as well as added space for associated nursing and support services. There is additional new construction involved with this project, which will extend floors one through four of that same southeast wing to increase the hospital's critical care bed capacity from 30 to 54 beds, an increase of 24 beds, add four new operating rooms, and expand a recovery room and associated ancillary mechanical space to support the operating rooms. There is also substantial renovation to the existing surgical intensive care unit, an existing operating room, the central operating supply room, the post-operative recovery room, and associated support space. All this is intended to correct various challenges that the hospital has realized related to the limitations of its physical plant capacity, which included numerous canceled or postponed surgeries, as well as frequent emergency room diversions. The hospital expects this entire project to be completed in October of 2006. The recommended MCE is just over fifty-five million dollars. That will be financed through a one hundred percent equity contribution from the hospital, and therefore there won't be any new debt to finance this project. The funding for community initiatives associated with this project is substantial. It is over 2.7 million dollars. That is over five years. It will provide for various community programs in the hospital service area, including emergency preparedness, prevention and wellness, as well as several priorities of the local community health network area, the CHNA, will enhance the health of youth in the various communities there. We recommend approval of this project with the conditions noted in the staff summary."

Mr. Page noted a correction for the record, on the staff summary, page 17: see Emergency Preparedness section, first paragraph, last sentence, add a period after the word "coordinator" and delete the rest of the sentence that reads "and the initiatives' administrative structure and oversight will be provided by the North Suburban EMS Consortium. Add the subtitle: "Examples Include:"

Mr. David Barrett, CEO of Lahey Clinic, addressed the Council. He said, "…Many of you know that Lahey Clinic is a multi-specialty group practice with 257 beds in Burlington and 10 in Peabody. The hospital in Peabody is about ten miles from Burlington. In our DoN application,

we have proposed an expansion of our Burlington facility only. That expansion would include 4 additional operating rooms, and 60 additional beds, including 24 intensive care beds. The additional beds are particularly important because the number of available beds north of Boston has declined 25% since the mid-1990s. At the same time, ambulance diversion has increased dramatically at hospitals in our region, including Lahey. The number one cause of ambulance diversion is the lack of available beds, especially intensive care beds, and especially for trauma patients. During the same period, since the mid-1990s, Lahey has seen a steady and dramatic increase in the number of patients seeking all types of care, including outpatient care, admissions, and surgery. Daily inpatient occupancy at the Lahey clinic now exceeds 90%, well beyond the optimum for the industry which is 75%."

Mr. Barrett continued, "The Lahey Clinic Burlington campus meets the primary and specialty needs of its surrounding communities. Over 60% of the Burlington residents alone have used Lahey Clinic in the last three years. In addition, Lahey is a major regional specialty referral center. Ninety percent of our patients come from a geographic area that spans all of eastern Massachusetts, southern New Hampshire and Maine. It is the only tertiary medical facility north of Boston and south of Lebanon, New Hampshire. Over the next ten years, demand for all health care services is projected to increase dramatically, and we are aware of the demographics of the baby boom population that is coming. Lahey Clinic already operates very near maximum capacity. We believe that the Clinic's plan to add sixty beds and four operating rooms is necessary to meet the health care needs of Burlington, its surrounding communities and even eastern Massachusetts over the next ten to twenty years. We welcome your hearing this morning, and we hope that you will be able to approve our application."

Ms. Karen Higgens, President, Massachusetts Nurses Association, addressed the Council. She said, "We are an organization of 22,000 registered nurses and health care professionals in Massachusetts, and we work in over eighty-five health care facilities in the Commonwealth. I like many others am a working nurse, working the front lines of health care…We have come here today to share our concerns and recommendations that is this and any future expansion of patient care services, in any hospital, take into account the component of care delivery and patient safety that has been too often overlooked or ignored, and that is registered nurse to patient ratios. Evidence to support our concerns was presented to this body by DPH a few weeks ago with the release of a report showing 76% increase in injuries, complications and errors in Massachusetts hospitals over the last seven years, with the majority of complaints dealing with lack of quality patient care and nursing care. While the industry and the Department's spin on this result is that it is due to better reporting, we, the nurses, are telling you that these shocking numbers are accurate, and validate what we have been witnessing over the past years. Here in Massachusetts, a recent survey by Opinion Dynamics, a respected independent research firm, provided localized evidence of the danger of understaffing in our state hospitals. Eighty-seven percent of nurses reported having too many patients to care for safely. Two out of three nurses reported an increase in medical errors due to understaffing. Two out of three nurses reported an increase in complications due to understaffing. One in two nurses reported readmissions of patients due to understaffing, and one in two – one out of every two nurses reported injury and harm to patients due to understaffing of registered nurses and one out of two nurses reported that poor staffing lead to longer stays for patients, which costs us even more."

Ms. Higgens continued, "The most alarming factor was that nearly one in three nurses reported patients' deaths directly related to having too many patients to care for. These findings are supported by extensive national research, as well, that support this position, which was studies that were done in the Journal of American Medical Association, the New England Journal of Medicine, and most recently, in the Institute of Medicine, which will make a direct correlation between RN to patient ratios and patient safety. Again, while we don't oppose the expansion, we think it is appropriate to consider it in all bed expansions required in light of the following information. We need to know the data on current staffing levels, and we are not talking about FTEs. You need to know, and to survey the findings on the daily RN to patient ratios, and the skill mix on the floors at Lahey Clinic. We recommend that you ask access to patient care data, including mortality and morbidity, records of medication errors, and patient falls. Hospitals are now required by JCAHO to provide and track some of this data as part of their accreditation process, and you need to get your hands on this data. You should ask for the projection on staffing ratios for these new units as proposed, as well as proposed skill mix on these floors. You should also ask for the patient classification system that is in place, and this system should mandate improvements in RN staffing, based on the patients' acuity on these floors. It is our understanding that Lahey has stated it has the information we have identified, and has stated its commitment to providing the RN personnel needed to staff these beds under their expansion and they will be able to provide quality patient care. However, it is our concern that Lahey has not shared this data with those making this decision at this time. It may be the case that, under the current law and the existing DoN regulations, the health policymakers are prevented from considering these factors in making this decision, and that the health care organizations are under no obligation to provide it to you. Our point here today is that merely taking their word for it does not make for sound health policy."

Ms. Higgens noted a bill that her organization is working to get passed by the Legislature – H1282, an Act to ensure Quality Patient Care and Safe RN Staffing, which would mandate by law specifically RN to patient ratios for all acute care hospital units and departments, as well as call for a standardized patient classification that will mandate improvement in staffing based on the acuity and other factors related to the patient. It will also require hospitals to file reports detailing much of the information we have described here today to the Department of Public Health.

In closing Ms. Higgens stated, "It is up to you, those of you who are in charge of monitoring and protecting the public health, to do whatever you can to protect patients in our hospitals from conditions that place them at unnecessary risk. Failure to do so is not only a mistake of public policy, it is truthfully a matter of life and death. We ask that you please, when you take into consideration expansions of any facilities, that we find a way to actually look at the data to prove that they, in fact, are able to staff these areas appropriately, and that it is not just an increase in beds, that we can actually take care of the patients that we are putting in them."

Mr. Page, Senior Analyst, responded, "We recognize the concern that the MNA has about the quality of care issues in acute care hospitals…However, the Department's current licensure regulation doesn't set specific RN to patient ratios for acute care hospitals. The regulations require that health facilities, including acute care hospitals, provide a sufficient number of RNs on duty at all times, to plan, supervise and evaluate nursing care, and that the number of RNs

assigned to each nursing unit be consistent with the types of nursing care needed by the patients, and the capabilities of the staff. We have consulted with our Division of Health Care Quality regarding complaints about possible patient incidents at Lahey in the past three years, that may have had some significance regarding the lack of professional staffing. There have been no complaints that relate to that at all. We feel confident in what we are recommending here, that this project go forward based on what we have seen."

Discussion followed Dr. Dreyer noted that the question of minimum staffing ratios is very controversial. Chair Ferguson interjected, "I think you will testify to your legislation and as we will at the proper time. That is not what this is all about and I don't want to go down that road today. I want to focus specifically on the application…."

Council Member Thayer, Jr. asked for clarification on interpreter services. Ms. Brunilda Torres, Director, Multicultural Health Unit, DPH, explained to the Council that her office is in discussions with Lahey to work out an interpreter services agreement. Chair Ferguson summed up the discussion, which included Council Members Sterne and Thayer, Jr., she said, "The issue is we looked at similarly situated entities. The penetration of the need for translation services was higher in most of those others. Therefore, the conclusion that the Department has drawn, is that there may have been a greater need than was addressed. Setting that aside now and going forward, the issue is how to make it comparable with other existing entities in terms of penetration of translation skills, and working with the hospital around trying to keep better track of it so that we know for a fact."

After consideration, upon motion made and duly seconded, it was voted: (unanimously) to approve **Project Application No. 4-3A58 of Lahey Clinic Hospital**, based on staff findings and with the modifications noted above concerning the interpreter services; that a copy be attached and made a part of this record as **Exhibit Number 14,773**. As approved, the application provides for new construction of a two-story addition on top of the 5th floor of the existing southeast wing to increase the Hospital's medical/surgical capacity from 227 beds to 263 beds (an addition of 36 beds), as well as add space for associated nursing and support services. Additional new construction will extend floors one through four of the existing southeast wing to increase the Hospital's intensive care bed capacity from 30 beds to 54 beds (an addition of 24 beds), add four new operating rooms, and expand a recovery room and associated ancillary and mechanical space to support the operating rooms. It includes renovations to the existing surgical intensive care unit, one existing operating room, central operating supply room, post-operative recovery room, and associated support space. This Determination is subject to the following conditions:

1. Lahey Clinic Hospital, Inc. shall accept the maximum capital expenditure of $55,271,000 (July 2003 dollars) as the final cost figure except for those increases allowed pursuant to 105 CMR 100.751 and 752.

2. The total gross square feet (GSF) for this project shall be 110,471 GSF: 97,480 GSF for new construction to add 36 medical/surgical beds, 24 intensive care beds, four operating rooms, add space for nursing and support services, and expand a recovery room and associated ancillary and mechanical space to support the operating rooms; and 12,991

GSF for renovation to the existing surgical intensive care unit, one existing operating room, central operating supply room, post-operative recovery, and associated support space.

3. Lahey shall provide the following elements of a professional medical interpreter service:

    - Dispatching and infrastructure support to the interpreter services coordinator to improve access
    - Outreach to the large non-English speaking communities in Lahey's modified service area to ensure their knowledge of Lahey's interpreter services
    - Periodic training on the effective use of interpreters and cultural competency to Lahey medical providers
    - Inclusion of protections for employee volunteers
    - Demonstration of consistent race, ethnicity and language data gathering
    - Annual language needs assessment for Lahey's modified service area
    - A plan to address these interpreter service elements shall be submitted to the Director of the DoN Program and the Director of the Office of Multicultural Health within 120 days of the DoN approval. In addition, progress reports shall be submitted annually to the Director of the Office of Multicultural Health on the anniversary date of the DoN approval.

4. Lahey Clinic Hospital, Inc. shall provide a total of $2,763,550 (July 2003 dollars) over a five-year period to fund the following community health service initiatives:

A. Emergency Preparedness:

Lahey will provide $156,500 per year over five years for a total of $782,500 to fund the following preliminary initiatives to ensure communication, training and collaboration for public health and safety for the Community Health Network Area (CHNA) #15 local communities in the event of a bio-terrorism event and/or natural disaster. The overall emergency preparedness initiatives will be finalized in consultation with the appropriate Massachusetts Department of Public Health Preparedness Coordinator.

Examples of Emergency Preparedness Initiatives Include:

1. Hazard Materials (HAZMat), Weapons of Mass Destruction (WMD), and terrorist awareness training funds available to support training programs that will encompass all CHNA 15 community Public Safety and Emergency Medical Service (EMS) personnel in area towns and cities, including salaries, course enrollment and

materials: $20,000/year

2. Staff time to conduct annual Mass. Decontamination Unit (MDU) exercise training for Burlington Police, Fire, EMS personnel and other CHNA 15 representatives, up to 25 people at $25/hour: $4,500/year

3. Incident Command Training (Massachusetts Fire Academy) will be available for town public safety officials in all CHNA 15 towns and cities, including salaries, course enrollment and training materials: $10,000/year

4. 911 Medical Dispatch, and communication support for area communities including those presented in CHNA 15, and involving dispatcher training and provision of protocols (card sets for the dispatch protocol are $400 per set and a class for a minimum 15 students is $1,500 for a three-day course): $15,000/year

5. Acquisition and/or re-supply of appropriate equipment to support community readiness and protection (AED's protective equipment, communications) in all CHNA 15 towns: $7,500/year

6. OSHA technician level 24 hour training for five staff @ $600 each: $3,000/year

7. Replacements of radios/walkie talkies and recording devises for CHNA 15 area towns and cities to communicate with Lahey Emergency Department: $15,000/year

8. N-95 respirator masks and fit test, and isolation protective gear for EMS personnel: $10,000/year

9. North Suburban EMS Consortium support for above initiatives:

a)	.5FTE Coordinator	$35,000
b)	.25 FTE Administrative Support	10,000
c)	Training Materials	10,000
d)	Training AV Equipment, Laptop/LCD Projector	10,000
e)	Indirect Overhead (10%)	6,500
		71,500/year

B. Prevention and Wellness Initiatives**:**

Lahey will provide $133,750 per year over five years for a total of $668,750 to fund the development and expansion of the following prevention and wellness initiatives involving the populations of CHNA 15. This will be done in consultation with Lahey's Community Benefits Initiative Committee, the Director of the

Department's Office of Healthy Communities, and up to three additional representatives from the Department (including but not limited to: Office of Elder Affairs, Adolescent Health, Community Health Promotion).

1. Collaborative efforts with the local Councils of Aging (COA) in CHNA 15 towns and cities to establish weekly exercise programs with three area COA's in CHNA 15 communities:

a) Instructor Salary $30,000

b) Administrative Support, Materials 5,000

2. Support prevention/screening programs at Burlington Council on Aging, which are designed to reduce hospitalization rates for the elderly:

a. Quarterly RN Screenings $10,000

b. Diagnostic Testing 10,000

c. MD Oversight and Consultation 15,000

3. Community health education/screening programs:

a. Organize educational seminars and lectures on a wide variety of health topics at various locations throughout CHNA 15 communities. These will serve targeted needs for the community at large and defined population groups including seniors and youth. In addition, an active speaker's bureau will be maintained and available to community groups to address local health risk concerns: $7,500/year

b. Provide support for a Registered Dietician dedicated toward ten diabetes education/screening programs with a focus on identifying high risk clients for referral: $7,500/year

c. Conduct annual Flu Clinic for CHNA 15 towns and cities. This will involve an estimated 2,500 vaccines @$8.50 per vaccine and 3RN's and 1 Administrative Support person: $41,250/year

d. Support smoking cessation courses for all populations in CHNA 15: $7,500 year

C. <u>At Risk Populations:</u>

Lahey Clinic will provide $36,000 per year over five years for a total of $180,000 to fund the following programs involving "at risk" populations in CHNA 15.

1. Domestic Violence – Funds will be utilized to support the ongoing education/awareness and support activities for Lahey's Domestic Violence Task Force: $15,000/year

2. Intergenerational Program – Funds will be utilized to expand an annual intergenerational program targeting seniors and teenagers that is designed to provide interactive experiences while focusing on positive behaviors: $8,000/year

3. "At Risk" Adolescents – Funds will be utilized to expand Health Adventures program involving area middle school students with programs designed to provide career exposure/guidance/counseling and group process training to 8th grade learning needs students:

a.	Transportation	$3,000
b.	Coordinator	5,000
c.	Materials	1,500
d.	Refreshments	1,500
e.	Miscellaneous	2,000
		$13,000/year

D. CHNA 15/Massachusetts Partnership for Healthy Communities Priorities:

Northwest Suburban Health Alliance (CHNA 15) includes the towns of Woburn, Burlington, Winchester, Wilmington, Bedford, Lexington, Lincoln, Concord, Carlisle, Acton, Boxborough, and Littleton. The CHNA is a broad-based local coalition of public, non-profit, and private sectors working together to build healthier communities through community-based planning.

CHNA 15 has worked with its members to identify short and long term needs, as well as a system of operating principles which include a vision and mission statement about how the CHNA decision making process operates. The CHNA has completed a strategic planning process, and develops an annual workplan. In the summer of 2003, the CHNA surveyed members to identify current areas of concern, and designed strategies to address these areas.

The top three areas which CHNA members identified as priorities for the youth in their communities included:

1. Alcohol/tobacco/drugs
2. mental health

3. poor nutrition leading to obesity and type 2 diabetes

The CHNA believes that the most important strategies for addressing these priorities fall into four categories, which include:

- Leadership Development – to address these priorities on the local level
- Professional Development Series – to develop skills for leaders in each community
- Grant Writing Workshops – to bring resources into the community to address critical issues
- Community Health Education and Forums – to mobilize the community to meet local and regional health needs

To assist the CHNA in identifying measurable outcomes and corresponding evaluation components based on the above four strategies, Lahey will provide $226,460 per year over five years for a total of $1,132,300 for the initiatives indicated below. Specific funding for these initiatives shall be allocated by the CHNA on an annual basis based on identified community priorities and readiness. The CHNA will determine the fiscal agent(s) for the funds. Lahey will also provide "bridge" funds in the amount of $37,000 on or about October 1,2004, provided that Lahey has committed to construction of the DoN approved project. Said funds would be housed with a non-profit organization. Subsequent years' funds will be delivered on October 1 of each year of the next four years.

1. Healthy Youth – CHNA 15 will provide mini grants via a Request for Proposal (RFP) process to assist CHNA 15 communities in developing healthy environments for youth. The grants will build upon established activities within the CHNA 15 communities that enhance the health of youth through reduction of substance abuse and unhealthy behaviors. The mini grants will be structured to support the use of evidence based models.

2. Train the Trainer Community Building – Funding will be used for 1) purchasing science based curriculum models and 2) training of individuals or groups from CHNA 15 communities in the use of the curriculum. Science based models will include but not be limited to substance abuse, dating violence, suicide prevention, and teen pregnancy prevention.

3. Healthy Community Pilot Projects - The CHNA will develop pilot projects in CHNA communities which according to the Youth Risk Behavioral Surveillance Survey (YRBSS) have higher rates of unhealthy behaviors. The communities will be provided with funding to enable them to initiate a Healthy Community process that will facilitate community change. This will include mobilizing leadership, identifying community indicators, prioritizing health issues, developing plans and strategies, and evaluating the

results.

4. Evaluation - Funds will be allocated to developing and implementing an evaluation plan for the proposed activities indicated above. This could include data collection and the use of logic models to identify both program and community outcomes.

5. CHNA Infrastructure Capacity - To create and sustain the capacity to develop and implement the above programs and initiatives, to assure a viable and representative coalition of CHNA 15 members, funds will be allocated to fund a CHNA15 coordinator position. In addition, other consultants may be hired for specific aspects of the plan, including but not limited to additional training opportunities for CHNA 15 members and communities.

6. Massachusetts Partnership for Healthy Communities - A minimum of $80,000 per year over five years will be directed to the Mass. Forum, which provides a statewide training and capacity building forum to assist community teams to implement a Health Communities process in their city or town. The funding will be allocated through the Partnership to support the Mass Forum's activities, which include but are not limited to scholarships for Forum participants, Forum training development and implementation, a community mentoring program, healthy communities topic clinics and technical assistance.

Lahey, along with CHNA 15 and the Massachusetts Partnership for Healthy Communities will hold an annual "Review Summit" of the community health initiatives as approved by the Public Health Council, for the purpose of evaluating the effectiveness of each component of the initiatives. In addition, Lahey, CHNA 15, and the Massachusetts Partnership for Healthy Communities will consider emerging health needs and allow for potential re-allocation of funds. However, Lahey and CHNA 15 reserve the right to make the final decisions as to how their respective portions of the funds are allocated. Progress reports shall be submitted annually by Lahey, CHNA 15, and the Massachusetts Partnership for Healthy Communities on the anniversary date of the DoN approval to the Department's Director of the Office of Healthy Communities.

Staff's recommendation of approval was based on the following findings:

1. Lahey Clinic Hospital, Inc. is proposing new construction of a two-story addition on top of the 5th floor of the existing southeast wing to increase the Hospital's medical/surgical capacity from 227 beds to 263 beds, as well as add space for associated nursing and support services. Additional new construction will extend floors one through four of the existing southeast wing to increase the Hospital's intensive care bed capacity from 30 to 54 beds, add four new operating rooms, and expand a recovery room and associated ancillary and mechanical space to support the operating rooms. Substantial renovation is also proposed to the existing surgical intensive care unit, one existing operating room, central operating supply room, post-op recovery, and associated support space.

2. The health planning process for the project was satisfactory.

3. The proposed new construction and renovation is supported by current and projected acute care utilization, as discussed under the Health Care Requirements factor of the Staff Summary.

4. The project, with adherence to a certain condition, meets the operational objectives factor of the DoN Regulations.

5. The project, with adherence to a certain condition, meets the standards compliance factor of the DoN Regulations.

6. The recommended maximum capital expenditure of $55,271,000 (July 2003 dollars) is reasonable compared to similar, previously approved projects.

7. The recommended operating costs of $13,953,163 (July 2003 dollars) are reasonable compared to similar, previously approved projects.

8. The project is financially feasible and within the financial capability of the applicant.

9. The project meets the relative merit requirements of the DoN Regulations.

10. The proposed community health service initiatives, with adherence to a certain condition, are consistent with the DoN Regulations.

11. The Julie Pinkham Ten Taxpayer Group (TTG) formed in connection with the project and requested a public hearing, which was held on October 9, 2003 in Burlington. Testimony presented at the hearing expressed concern about the impact of low nursing staff to patient ratios on quality of care at acute care hospitals, including Lahey.

COMPLIANCE MEMORANDUM: PREVIOUSLY APPROVED DoN PROJECT NO. 6-3942 OF NORTH SHORE MEDICAL CENTER-UNION HOSPITAL – Progress report on compliance with conditions of approval for transfer of ownership

Ms. Joyce James presented Staff's report on the compliance of the previously approved project 6-3942 of North Shore Medical Center. She said in part, "…Presented today for your consideration is Staff's progress report on North Shore's Medical Center Union Hospital's compliance with six conditions of approval of Approved DoN Project No. 6-3942, the Transfer of Ownership in which Union Hospital – North Shore Medical Center became the sole member of Union Hospital. These six conditions relate to statutory free care, primary care, free physician specialty and pharmacy services, community outreach, substance abuse, and mental health services. Staff's report is based on annual progress reports submitted by North Shore Medical Center and Lynn Health Task Force, as recommended by the Council at its March 2002 meeting that Staff's reports should be based on these annual progress reports that were submitted in October and November 2003, respectively by North Shore and the Task Force. Based on these,

we find that North Shore Medical Center is in full compliance with the statutory free care conditions, and is in significant compliance with the remaining five conditions.

Ms. James continued, "The issue of governance was not scheduled to be part of this report. However, the issue was raised because of the planned consolidation of the Board of Trustees of hospitals that are under the North Shore Medical Center Corporation. The Task Force has raised some questions concerning whether or not this consolidated board should be consistent with the governance condition which Council has found that the hospital was in compliance with in previous reports. Our comment on this is that we are pleased that the hospital was willing to reopen the governance condition in discussions with the Task Force. Based on our findings, we recommend that the Task Force and North Shore Medical Center return in one year to the Public Health Council with a report on its progress in complying with five conditions relating to primary care, free specialty physician and pharmacy services, substance abuse, mental health, and community outreach…"

Next, Mr. Robert Norton, President and Chief Executive Officer of North Shore Medical Center spoke. He said in part, "…I am pleased to report once again, on our substantial and concrete progress on the outstanding conditions, and most importantly, our continued and strong relationship with our colleagues at the Lynn Health Task Force. This relationship will be elevated to a new level in another month or so, when we consolidate the two acute hospitals into one. Task Force members will join the North Shore Medical Center governance structure at that point. First, with respect to the outstanding conditions, I would like to highlight areas of significant achievement and our ongoing work in these areas. In primary care, after years of intensive work on this project, we were able to celebrate the grand opening of a new primary care site in West Lynn in October. North Shore Medical Center and Partners Health Care have contributed 6.5 million dollars to this important project which enables the Lynn Community Health Center to bring much needed bilingual primary care and behavioral health services to this underserved area of Lynn. It has also enabled us to fulfill our commitment in the conditions to bring ten new primary care physicians to Lynn. Nine are in place now. A tenth will be added in mid 2004...."

Mr. Norton continued, "The second condition of free care, specialty and pharmacy services, I am pleased to report that, with a great deal of hard work, creativity and dedication among ourselves, the Task Force and the Centers, we have made significant progress on increasing specialty physician access and pharmacy service. This increased access has not only been impressive in its own right, but has been noted as a possible model for other community hospitals within the Commonwealth, as well. We are however, at a stage where we need help to continue to make it possible for free care patients to receive the care they need and deserve in a way that is coordinated, culturally competent, and high quality. We believe we are in a unique situation at North Shore Medical Center to work with the Task Force and our colleagues at the local community health centers to put such a care model together for our free care patients. We are going to be increasing our efforts in this regard over the next several months…We believe this is a very important priority for, not only the North Shore Medical Center, but for care of the growing uninsured population in general. We are likely to call on the Department and others in State government…as we put together the design of this care model, working with the State to

enable free care patients to access appropriate care and appropriate sites, with appropriate ease. The support of state agencies will be critical as we move forward."

Mr. Norton continued, "…Many patients requiring care, who are patients eligible for free care, end up in our emergency departments. Those are clearly not the right places to provide that care and therefore we want to be able to work more creatively with the health centers in our service area to try to get that care provided in the lowest cost, most effective setting that we can….With regard to mental health, substance abuse, and community outreach, we believe our accomplishments in these areas are significant and reflect a central compliance…Finally, we are in the process of consolidating the two acute care hospitals, Salem and Union. That consolidation is scheduled to take place in January 2004…We have had many discussions with the Task Force over the past few months on how we can best preserve the principles underlying the original Union Hospital Governance condition as we go forward with one board…The Task Force will have three seats on our newly formed Community Affairs and Community Health Access Committee. This Board Committee will play a major role in determining how we can best use our resources to meet the growing needs of all patients we serve. We do this work in an environment in which the needs of our patients are growing rapidly, particularly those patients who are uninsured and underinsured, and it will take our collective creativity to stay ahead of this trend."

"We have come a long way in the work that we have done here. We have all come to appreciate how much more we can accomplish together, and it is in that spirit that a unified North Shore Medical Center welcomes the Task Force to its governance infrastructure, and rededicates itself to doing all that we can to serve all, and I emphasize, all of the patients in the North Shore."

Ms. Marsha Hahns, Steering Committee Member, Health Care for All said in part, "…Health Care for All works with many community organizations around the state and we think that the Lynn Health Task Force has been a role model in this state for a very committed and organized approach to community needs and access issues, and protection of the safety net, and also for forging very collaborative relationships with the hospital, the health center, and other agencies in the city."

Attorney Steve Rosenfeld, Member of Health Care for All, Lynn Task Force Legal Counsel, said in part "…I am counting my seventh appearance with the Lynn Health Task Force as their legal counsel, there are some new members, it has really been the combination of the rigor and hard work of the Lynn Health Task Force, together with the leverage that has been provided by the support and the interest of the Public Health Council that has allowed us to make the progress that we have made in Lynn."

Ms. Diane Kuziahills, Substitute for Leslie Greenberg, said in part, "…We are very happy to come here again. Our annual reporting to you helps us to solidify what we have done in the past year…I would like to focus on three issues that we feel are the most important issues that we are bringing to you this year. The first issue is the issue around statutory free care. When the hospital transferred their license, both the law and the regulations say that they have to maintain the level of free care that was provided at the hospital. At AtlantiCare at the time, their percentage was 4.24 percent, and in the intervening years, the hospital has never quite made it to

that level. They have had bad years where I think the level was 2.9 percent, but we have never really achieved the same level of free care that AtlantiCare had before they merged with North Shore Medical Center. In the staff report, they mentioned changes in MassHealth eligibility, which makes it difficult to still provide that level of free care. They said to you they think that they are in compliance with that requirement, and that they want to get rid of that condition of 4.24 percent, and we actually respectfully disagree with that recommendation. We know that yes indeed, in 1997, the MassHealth expanded, and there were many more people that were on Medicaid, but as you all know, many of those people have been removed from Medicaid roles, eleven thousand people have been removed from Medicaid roles, eleven thousand immigrants. Lynn is a community that has many immigrants that were cut off from MassHealth roles. MassHealth Basic was eliminated and now is coming back in a smaller form, and I think it is wrong to really assume that those changes in 1997 still apply today. There are many people who need free care, and we see many people showing up, and I am sure you would hear from the Community Health Center that that is true. What we are asking you is that, if indeed you think the 4.24 percent is not achievable, we want there to be a rational way of looking at what that level should be, and that means looking at demographics in the City of Lynn, and really looking at it, not just saying, okay, let's eliminate it, but let's pick a number that is reasoned, and based on data, and I think our assumption is that you will find that the level needs to remain pretty close to the 4.24 percent."

Chair Ferguson asked two questions: Are people being turned away? Are translation and transportation services being eliminated? Ms. Kuziahills replied, "I don't think so. I think it takes continued effort to make sure that things really happen like enrolling people in free care. We have done enrollment efforts where we have really gone out to the community. There are things you can do to make free care really accessible…having the sort of universal enrollment, where someone enrolls at the Health Center in free care, they can also use it at the hospital. Our feeling is that there are ways to make free care better and not just assume that people will come and ask for it, but to really do outreach and design programs around increased participation in free care."

Chair Ferguson added, in part, "…I think we have a bunch of policies conflicting with each other. There is a whole series of activity around the free care pool, and how we are going to go forward in terms of what is covered and what is not covered, and a lot of the eligibility criteria. I think what I am trying to get a feel for is what your underlying goal is. If your underlying goal is to make sure that people who are in that area have adequate care, that goal could be achieved in a variety of ways, not necessarily by ensuring that x percent of care provided from the hospital is though the free care pool, but possibly rather taking the dollar amount that it is equivalent to, indexing it, and making sure that the system as a whole is providing that level of service to the community and to the folks without insurance. In other words, there are a number of different ways of making sure that the same amount of money is provided in the most appropriate setting and that is what I would be more inclined to want to do, rather than a percentage at the hospital level because I just think the truth of the matter is that that could dramatically change in the next two years, based on what we do in the free care pool."

Ms. Diane Kuzihills, responded in part, "I understand what you are saying. One of our perspectives is that, having that as a percentage of the gross patient revenue of the hospital sets

up a benchmark that people strive for. If there is no benchmark, not as much effort and work really happen in making sure that the hospital is really accessible to people who need free care…"

Chair Ferguson said "I guess that what I would pose as a view about this particular issue is to come up with a specific proposal, as opposed to eliminating the percentage…Come up with a specific proposal that relates to how we will maintain the commitment and to make sure the commitment can go as far as it possibly can. I am not inclined to go to a percentage of free care commitment. I think that that exacerbates the existing set of incentives in the system that does not work. So, I think getting back to what it is that we want to achieve in Lynn, specifically around coverage, or whatever the issue is, and that is what it ought to be focused on, and there should be some agreement on what that level specifically needs to be."

Ms. Diane Kuziahills said further, "I think that is all we are really asking is that there is a dialogue around that, that it is not just anecdotal…We are eager to have a conversation about other ways to ensure that there is adequate treatment. We are eager to work on that issue….The second issue I wanted to bring up was around primary care. The staff reported that there is a great expansion that the Task Force really applauds, and I think our request to you is that we keep that commitment as something we are going to be talking about next year because, where in the original conditions it says that they were needing to add between ten and thirty primary care physicians in the community, we have made it to the ten level. That is the very lowest level that we could possibly achieve, and we think that there might be room somewhere between ten and thirty that we need to work for, and when we originally did the negotiations on all these conditions, the City of Lynn had a smaller population than they have today. I think it is something that we need to revisit, and we would like to keep it on the table and come back next year…The third issue that we want to invite you to come back next year and talk to you about is governance, and as you can see from the staff report, there are some concerns, undergoing a major change, the two hospitals are merging, and the DoN conditions that we had ensured that the Lynn community would have a role in the governance of the hospital…We really would like to be able to have the opportunity next year to come back and talk to you next year and report whether there is progress.…"

Attorney Steve Rosenfeld added, "Regarding what is before the Public Health Council from year to year, I would just strongly recommend that the jurisdiction be kept as broad as possible because, just having this reporting requirement has played such an important role in sustaining what can sometimes be a difficult relationship. It has evolved as a very positive one, but issues do arise. So when you take something off the table, like governance, it then narrows the jurisdiction of the Public Health Council in a way that is really not constructive. "

Dr. Paul Dreyer, Assistant Commissioner, Interim Assistant Commissioner, Center for Health Quality Assurance and Control, said in part, "On the statutory free care question, I think the reason we wanted to eliminate that requirement basically for the reasons the Commissioner mentioned. It is really a technical regulatory requirement that does not have any necessary relationship to what the hospital was actually doing to ensure access to the citizens, and the number can vary for a number of factors that have nothing to do with what the hospital is doing. It can depend simply on the mechanics of the pool. It has nothing to do with the hospital's

behavior. So, I think Staff would certainly be willing to ask the hospital to come back to report more generally on efforts to ensure access to the citizens of Lynn.

Chair Ferguson responded in part, "…The truth is that hospitals can affect the use of free care pools. So, I would like you to sit down with the Task Force and the Hospital and talk about different ways to approaching that, and come back with a list of suggestions if that is alright with the rest of the Council...." Discussion continued and Chair Ferguson said, "I think the point is to be able to make a similar penetration in terms of caring for people at the level that they were caring for them prior [to the merger]. I am not in favor of doing it in percentages, but what I am suggesting is that there has to be another way to look at that…"

Dr. Dreyer said in part, "I was going to suggest that we mutually agree upon a metric for comparing past data with present data and come back to report on that metric. That is one option. The other option is we come back to the Council with that metric in the interim.

Chair Ferguson responded, "I am concerned about the use of a metric. I guess I am in a different place. I am not in a metric place. Maybe this is inappropriate for what we are trying to achieve but, I am at an outcome place. I am not about trying to figure out how to translate 4.9 percent as some metric as much as I am about finding a way to help the hospitals and the staff come together around mechanisms to achieve care across the continuum. Maybe that is just another way of saying what you said, and maybe the best way of approaching it is to say that you guys should get together and come back in a year with not only an agreement, that you have reached a [decision or compromise]of how this should go." Note: Technical difficulties occurred at this point with the tape cassette. Discussion continued Chair Ferguson instructed staff to return in a month with an amendment on this issue. Dr. Dreyer suggested that staff return in two months.

After consideration, upon motion made and duly seconded, it was voted unanimously to approve staff recommendation with Commissioner Ferguson's modification instructing staff to come up with an alternative to the free care percentage and return in two months with an amendment. It was noted that staff's recommendation on governance was accepted.

The meeting adjourned at 12:45 p.m.

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Christine C. Ferguson, Chair
Public Health Council

LMH/SB